510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

k120744

B. Purpose for Submission:

Clearance of new device

C. Measurand:

Assayed hematology parameters: WBC-BF (10^3/µL), RBC-BF (10^6/µL), MN# (10^3/µL), PMN# (10^3/µL), MN% (%), PMN% (%), TC-BF# (10^3/µL)

D. Type of Test:

Quantitative

E. Applicant:

Streck

F. Proprietary and Established Names:

XN-CHECK™ BF

G. Regulatory Information:

1. Regulation section:

   21 CFR § 864.8625, Hematology quality control mixture

2. Classification:

   Class II

3. Product code:

   JPK, mixture, hematology quality control

4. Panel:

   Hematology (81)

H. Intended Use:

1. Intended use(s):

   XN CHECK BF is used for control and calibration verification of Sysmex XN (XN-10, XN-20) analyzers. It is not, however, intended for actual calibration of these analyzers. Assayed parameters are: WBC-BF (10^3/µL), RBC-BF (10^6/µL), MN# (10^3/µL), PMN# (10^3/µL), MN(%), PMN(%), TC-BF# (10^3/µl).

2. Indication(s) for use:

   Same as intended use

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   Sysmex XN (XN-10, XN-20) analyzers

I. Device Description:

XN CHECK™ BF body fluid control is an in-vitro diagnostic product that contains the following: stabilized red blood cell component(s) and stabilized white blood cell component(s) in a preservative medium. The control includes two levels (i.e. low and medium) which are packaged separately in polypropylene plastic vials with screw caps containing 3 mL. The vials will be packaged in (4) welled vacuum formed clamshell container with the Instructions for Use / assay sheet. The product must be stored at 2 - 8°C.

J. Substantial Equivalence Information:

1. Predicate device name:

   Cell-Chex™ Auto, manufactured by Streck

2. Predicate 510(k) number(s):

   k053362

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	XN CHECK BF is used for control and calibration verification of Sysmex XN (XN-10, XN-20) analyzers. It is not, however, intended for actual calibration of these analyzers. Assayed parameters are: WBC-BF ($10^3/\mu L$), RBC-BF($10^6/\mu L$), MN# ($10^3/\mu L$), PMN# ($10^3/\mu L$), MN(%), PMN(%), TC-BF# ($10^3/\mu L$).	Cell-Chex™ Auto is an assayed whole blood control for evaluating the accuracy and precision of hematology instruments that measure blood cell counts in patient body fluid samples.
Open-vial stability	30 days	Same

Differences		
Item	Device	Predicate
Reagents	XN CHECK BF contains the following: stabilized red blood cell component(s) and stabilized white blood cell component(s) in a preservative medium.	Cell-Chex™ Auto contains stabilized human red blood cells and white blood cells in a preservative medium.
Control levels	2 levels	3 levels
Closed-vial stability	84 days	75 days
Storage conditions	2 - 8°C	2 - 10°C

K. Standard/Guidance Document Referenced:

CLSI H26-A2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, October 2010.

CLSI EP5-A2 Methods, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition.

L. Test Principle:

Bi-level XN CHECK™ BF was designed to evaluate the accuracy and precision of the Sysmex XN Series instruments. XN CHECK™ BF is for in-vitro diagnostic use only by laboratory professionals.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Data were collected internally and at two external sites across 4 different

Sysmex XN-10 and XN-20 analyzers, throughout the product dating claim with 3 separately manufactured lots of XN-CHECK™ BF. Studies were conducted for each lot at all three (3) sites. The external sites performed 10 consecutive runs on each XN Series Instrument with separate vials of control from each lot. Control materials were shipped, stored, mixed, and handled in accordance with the Instructions for Use (IFU). Acceptance criteria were based on a compilation of the CV% for each measurand. Results collected across the three separately manufactured lots of XN CHECK™ BF demonstrated consistent recovery across multiple instruments at multiple sites and were within the parameter specific assay assignment ranges set forth for each measurand (see table below).

LEVEL-1							
Lot #	**Measurand (%CV)**						
	WBC-BF	**RBC-BF**	**MN#**	**PMN#**	**MN%**	**PMN%**	**TC-BF#**
1185	4.11	3.83	14.03	7.55	12.09	7.58	4.11
1241	4.73	3.69	8.89	5.63	7.13	3.42	4.73
1297	3.78	3.40	7.48	5.47	6.53	3.87	3.78
Maximum CV% Acceptance Criteria	10	10	N/A	15	15	10	10

LEVEL-2							
Lot #	**Measurand (%CV)**						
	WBC-BF	**RBC-BF**	**MN#**	**PMN#**	**MN%**	**PMN%**	**TC-BF#**
1185	4.92	3.40	11.48	13.83	10.63	7.31	4.92
1241	3.52	2.98	7.12	3.58	5.12	2.57	3.52
1297	11.07	3.16	5.61	4.11	4.17	2.62	3.38
Maximum CV% Acceptance Criteria	15	5	N/A	N/A	15	15	10

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Value assignments:
Streck performed analyses on four Sysmex (XN-10 and XN-20) analyzers using two vials of each level of control, tested a minimum of five times per vial. Data were entered into the internally validated QC link database program (validation number PQ-062) to calculate the mean, standard deviation (SD), and coefficient of variation (CV) for each parameter analyzed.

The database allows computation and comparison of data that is used in the assay value assignment process as defined by controlled documents. Expected range values assigned to each measurand were based on ± 3.0 SD calculated from the total-run data collected. Total-run encompasses the values generated over multiple combined datasets compiled for all three lots of control.

Reagent Stability

Acceptance criteria for open and closed vial stability were based on compilation of the CV% for each measurand on data collected across four different Sysmex XN-10 and XN-20 analyzers, at 3 sites, throughout the product dating claim, with three separately manufactured lots of XN CHECK™ BF.

Open-vial stability:

30-day open-vial stability claim was validated at the end of the 84-day closed vial product expiration claim on Sysmex XN-10 and XN-20 analyzer. Two vials of each level of control from each of the three reference lots were analyzed in duplicate at multiple testing intervals over a period greater than 30 days. On a daily basis, vials were removed from storage and mixed in accordance with the instructions for use to simulate daily customer usage/handling.

Closed-vial stability:

Three separately manufactured lots of XN CHECK™ BF lots were set up to validate closed-vial stability performance throughout the 84-day expiration dating at refrigerated temperature (2 - 8°C). Data were collected using CLSI EP5-A2 methods on Sysmex XN-10 and XN-20 analyzers.

All reported CV% values for open and closed-vial reagent stability were within the acceptable threshold values as shown in the tables above in section M. 1(a).

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The end-user is instructed to refer to the product assay sheet accompanying the product instructions for use.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.